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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,083	04/16/2004	Rashida A. Karmali	134.004	9955

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EXAMINER	
WARDEN, JILL ALICE	
ART UNIT	**PAPER NUMBER**
1743	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,083	KARMALI, RASHIDA A.	
	Examiner	Art Unit	
	Jill A. Warden	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm in view of Nason (4,978,504) and further in view of White (4,214,874).

Schramm teaches a method and kit for collecting samples of liquid specimens for analytical testing. See figures 2, 4 and 5. The device includes a sample container (5) with an open top (9) and a lower capillary end (4), an immunoassay test strip (12) and a vial containing reagents and/or buffers. The vial is sealed with a penetrable foil. The lower end of the container has an inwardly extending portion (6) that forms an air-tight seal with the vial. Figures 3-5 show how the device is used. See also column 4, lines 15-42. Capillary

volume capacity is given in column 3, lines 29-31. Schramm does not teach a filter in the container, does not cite specific materials of construction, does not teach colorimetric analysis and does not teach a coated capillary.

Nason teaches a specimen test unit, see figures 12-15. The device includes top (14) and bottom caps (60) containing a swab sampling element (20) in a housing (30) . The housing includes a filter for filtering samples and reagents that flow into the housing and to the collection vial. The housing is made from plastic to accommodate deformation (column 5, lines 58-62). Nason discloses colorimetric analysis on reaction products in a vial in column 9, lines 19-25 and column 10, lines 20-25. It would have been obvious to one having ordinary skill in the art to modify Schramm to provide a plastic structure for deformability and resiliency. With respect to the caps, it would have been obvious to one having ordinary skill in the art to provide caps to seal the body structure of Schramm. With respect to the filters, it would have been obvious to one having ordinary skill in the art to modify the device of Schramm to include filters to trap components or provide reagents, as suggested by Nason (column 8, lines 5-15), One would provide for colorimetric analysis within the device in order to provide an easily understood analysis method of the contents inside in order to avoid transfer of materials from the device. This would safeguard the operator and provide a single use, self-contained collection and analysis device.

Schramm and Nason do not teach coating the capillary.

White teaches a capillary tube for blood collection (see column 2, line 51 through column 3, line 17). White teaches that the interior of the tube is coated

with an anticoagulant. Capillary attraction is used to fill the tube with blood. It would have been obvious to one having ordinary skill in the art to provide an anticoagulant coated on the interior of the capillary portion of the modified device of Schramm in order to minimize clotting from the sample being drawn through the capillary portion. Schramm and Nason include an immunoassay device. One would add the anticoagulant to ensure blood flow into the device. As for the graduated markings on the capillary, White also teaches these are conventional. It would have been obvious to one of ordinary skill in the art to add markings for volume.

Claim 12 recites a plurality of containers having color-coded identifiers. Providing a plurality of containers to perform a number of different tests would have been obvious to one of ordinary skill in the art to provide increased throughput without any cross-contamination.

Response to Arguments

Applicant's arguments filed March 19, 2007have been fully considered but they are not persuasive.

Applicant argues that a capillary pipette in not analogous to applicant's. Examiner disagrees. Applicant's capillary is used collect sample and to introduce that sample to the device. White specifically teaches using a coated capillary for sample collection. This is indeed, analogous.

Applicant argues that the specific serial placement and the shape of the filters in Nason also distinguish it from the instant claims. Examiner disagrees. Applicant has recited a filter in the proximal end of the device. Schramm is

modified by Nason to teach a filter in the proximal end. The specific number of filters, and the specific shape of the filters do not distinguish the device from that of the instant claims. The claim is written in open language, which does not preclude additional elements. There is no specific contour required by the claims. Therefore, any disclosed contour meets the filter limitations.

Applicant argues that the claimed invention is not an EDTA coated capillary pipette. Applicant claims a capillary which transfers sample from a subject to the device. This, in simple form, is a pipette. As far as the EDTA is concerned, this is a well-known preservative. Examiner believes that applicant is claiming a capillary pipette as part of the device.

With respect to the plural specimen collecting devices included and packaged together, again, examiner believes that such packaging would have been obvious to one of ordinary skill as a means to increase sample testing and throughput.

Applicant argues that there is no teaching or suggestion in the references that a specimen collecting and analytical assembly can be improved by combining the elements of the prior art references. Examiner points out that combining the references does not have to provide an improved device. Equivalent alternatives are also considered obvious modifications of a prior art device. But it is also noted that some of the changes proposed by the examiner are indeed useful improvements and sufficient motivation to make these changes was provided in the rejection.

Applicant argues that one of ordinary skill in the art would not have coated the inside of a capillary tube because it would interfere with the capillary force needed to draw the blood sample into the tube. Examiner disagrees. The capillary (micro) pipette of White is coated. Such has been conventional for quite a while.

Applicant submitted 2 declarations with the response. One has been previously addressed in the advisory of January 18, 2007. The second declaration is in response to the examiner's comments in the advisory and states,

"applicant is amazed that this senior examiner would ask for an economic report on cost savings when one with ordinary skill in the art can clearly understand that a collecting device for 5ml or 10 ml of blood will require a larger tube, larger amounts chemicals and higher prices per tube than a smaller collecting device, smaller amounts of chemicals and lower prices per tube were used to collect 2ml blood. Applicant is not only the CEO of her company SavviPharm Inc, but the CFO. However, this examiner finds it hard to believe anything applicant states and labels it as 'just conclusions'."

With respect to experiments on the capillary coating, Applicant also states,

"In fact, it was after several attempts that we standardized the coating of the capillary tube so the coating material(s) did not interfere with the drawing of the specimen or block the opening of the capillary tube. The experiments that we conducted involved dissolving the anticoagulants in either water, alcohol or saline and then layer the internal of the capillary tube. We found that saline and alcohol were not appropriate vehicles to dissolve the anticoagulants because somehow, the capillary suction was slower. We also found that the capillary action was faster when we avoided layering the extreme tip of the capillary."

Examiner reiterates that declarations must be accompanied by evidence.

Without evidence of the actual experiments conducted or the data which

supports the commercial success, the declaration is not probative. See MPEP 716.

Conclusion

Any inquiry concerning this communication should be directed to Jill A. Warden at telephone number (571) 272-1267.

Jill A. Warden
SPE
Art Unit 1743